

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

PAMLAB, L.L.C., METABOLITE
LABORATORIES, INC., and
BRECKENRIDGE
PHARMACEUTICAL, INC.,

Plaintiffs,

v.

VIVA PHARMACEUTICAL, INC.,

Defendant.

CASE NO. C12-98MJP

ORDER DISMISSING
DEFENDANT'S COUNTERCLAIM
FOR INEQUITABLE CONDUCT

This matter comes before the Court on Plaintiffs' motion to dismiss the inequitable conduct counterclaim brought by Defendant Viva Pharmaceutical, Inc. (Dkt. No. 20.) Having reviewed the motion, Defendant's opposition (Dkt. No. 21), Plaintiffs' reply (Dkt. No. 22), and all related filings, the Court GRANTS Plaintiffs' motion and DISMISSES Defendant's counterclaim for inequitable conduct.

Background

Plaintiffs Pamlab L.L.C., Metabolite Laboratories, Inc., and Breckenridge Pharmaceutical, Inc., file a motion to dismiss the counterclaim brought by Defendant Viva Pharmaceutical, Inc., pursuant to Federal Rules 12(b)(6) and 9(b). (Dkt. No. 20 at 4.) The counterclaim at issue seeks a declaratory judgment of patent unenforceability based on alleged inequitable conduct before the U.S. Patent and Trademark Office (“PTO”) related to the prosecution of U.S. Patent 6,528,496 (“the ‘496 Patent”), the single patent at issue in this lawsuit. (Id.)

The counterclaim here is unique because, rather than being based on Defendant’s own investigation, Defendant simply copies the factual allegations contained in a separate lawsuit between two of the current Plaintiffs. (Id.) That suit, a 2006 Florida district court case between Breckenridge and Metabolite, settled following a claim construction ruling by the court, and Breckenridge eventually became a sublicensee of the ‘496 Patent. Breckenridge Pharm., Inc. v. Metabolite Labs., Inc., Case No. C04-80090-JIC, Dkt. No. 174-1 (S.D. Fla. Dec. 1, 2006.); (Dkt. No. 20 at 4).

The patent at issue in this case covers various combinations of vitamins B6, B12, and folic acid in order to treat hyperhomocysteinemia, a risk factor for arteriosclerosis and coronary heart diseases. (Dkt. No. 1 at 3.) The ‘496 Patent was obtained in 2003 by two hematology professors at the University of Colorado School of Medicine, Dr. Robert H. Allen and Dr. Sally P. Stabler. (Id. at 4.) Dr. Allen formed Plaintiff Metabolite under the University of Colorado’s guidelines, and the ‘496 Patent was assigned to Metabolite. (Id.) In 2000, Metabolite granted Pamlab an exclusive license to certain formulations under several related patents and applications, one of which, through a continuation application, issued as the ‘496 Patent. (Id.)

Pursuant to the license, PamLab manufactures and sells a product called “Foltx,” which contains three active ingredients: 2 mg of vitamin B12, 25 mg of vitamin B6, and 2.5 mg of folic acid. (*Id.* at 5.) Plaintiffs allege that the ‘496 Patent is infringed by Defendant’s folic acid product, which contains the same compounds as the PamLab product. (*Id.* at 6.)

Defendant’s counterclaim for inequitable conduct alleges that inventors Stabler and Allen “were knowledgeable about all the prior art in their field and had express knowledge of material prior art, which was not disclosed to the PTO and which, if such art had been disclosed, would have resulted in the continued rejection of the patent applications” (Dkt. No. 8 at 15-16.) Defendant alleges that Plaintiffs’ patents “are unenforceable because of [Plaintiffs’] intentional omissions and/or misrepresentations made to the Patent Office and which were materially related to the claims ultimately patented in the Patents.” (*Id.* at 39.) Defendant concludes that, but for these intentional omissions and/or misrepresentations, the Patent Examiner would not have allowed the invention claimed in the applications that ultimately issued as the ‘496 Patent. (*Id.* at 39-40.)

Discussion

A. Legal Standard

When deciding a motion to dismiss under Federal Rule 12(b)(6), the Court must accept all factual allegations in the complaint as true and draw all reasonable inferences in the non-moving party’s favor. See *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001). Further, “to survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

A claim for inequitable conduct is reviewed under Federal Rule 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009). Rule 9(b) requires that, in alleging fraud,

1 a party must state with particularity the circumstances constituting the fraud. Fed. R. Civ. P. 9(b).
2 “[T]o plead the circumstances of inequitable conduct with the requisite particularity under Rule
3 9(b), the pleading must identify the specific who, what, when, where, and how of the material
4 misrepresentations or omissions committed before the PTO.” Exergen, 575 F.3d at 1329. Rule
5 9(b) states that “[m]alice, intent, knowledge, and other conditions of the mind of a person may be
6 averred generally.” Fed. R. Civ. P. 9(b). The relevant conditions of mind for inequitable conduct
7 include: (1) knowledge of the withheld material information or of the falsity of the material
8 misrepresentation, and (2) specific intent to deceive the PTO.” Exergen, 575 F.3d at 1327.

9 For the “who” in an inequitable conduct claim, the pleading must name specific
10 individuals associated with the filing or prosecution of the application issuing as the patent who
11 both knew of the material information and deliberately withheld or misrepresented it. Id. at 1330.
12 For the “what and where,” the pleading must identify which claims, and which limitations in
13 those claims, that the withheld references are relevant to, and where in those references the
14 material information is found. Id. For “why and how,” the pleading must identify the particular
15 claim limitations, or combinations of claim limitations, that are supposedly absent from the
16 information of record. Id.

17 Inequitable conduct is an equitable defense to patent infringement that, if proved, bars
18 enforcement of a patent. Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1285
19 (Fed. Cir. 2011) (en banc). To prevail on the defense of inequitable conduct, the accused
20 infringer must prove that the applicant misrepresented or omitted material information with the
21 specific intent to deceive the PTO. Id. at 1287. “In other words, the accused infringer must
22 prove by clear and convincing evidence that the applicant knew of the reference, knew that it
23 was material, and made a deliberate decision to withhold it.” Id.

1 Intent and materiality are separate requirements. Id. “Proving that the applicant knew of a
2 reference, should have known of its materiality, and decided not to submit it to the PTO does not
3 prove specific intent to deceive.” Id. A court may infer intent from indirect and circumstantial
4 evidence, but “the specific intent to deceive must be the single most reasonable inference able to
5 be drawn from the evidence.” Id. (internal citations omitted). “[I]n assessing the materiality of a
6 withheld reference, the court must determine whether the PTO would have allowed the claim if it
7 had been aware of the undisclosed reference.” Id. at 1291.

8 B. Intent and Materiality

9 Defendant’s counterclaim for inequitable conduct fails to meet the heightened pleading
10 requirements articulated by the Federal Circuit in Therasense and Exergen. 649 F.3d at 1285;
11 575 F.3d at 1329-30. All eleven examples of misrepresentations or omissions offered by
12 Defendant either lack sufficient specificity or are not plausibly alleged to be material.
13 Defendant’s counterclaim for inequitable conduct therefore fails.

14 1. Multi-Vitamin Prior Art and PDR References

15 In paragraphs 46-62 of the counterclaim, Defendant points to certain entries in the
16 Physician’s Desk Reference (“PDR”) for the years 1981, 1982, and 1990, alleging that these
17 references disclose “many examples of multiple vitamins containing all three vitamins” relevant
18 to the ‘496 Patent. (Dkt. No. 8 at 17.) But Defendant offers no facts showing that Allen, Stabler,
19 or anyone else actually knew of this specific information. (Id.) “[O]ne cannot assume that an
20 individual, who generally knew that a reference existed, also knew of the specific material
21 information contained in that reference.” Exergen, 575 F.3d 1312 at 1330.

22 In paragraph 62 of the counterclaim, Defendant asserts that “[t]he above identified
23 products were known to the Inventors, including Robert Allen, individually and/or Attorney
24 Beaton before December 1991, in light of the fact that they were listed in a publication

1 referenced by inventors Stabler and Allen.” (Dkt. No. 8 at 18.) However, the deposition
2 testimony that Defendant points out does not show that Stabler or Allen had any direct
3 knowledge of the products. (Dkt. No. 8-3 at 31-32.) Instead, the referenced deposition testimony
4 of Dr. Allen simply contains an acknowledgement that Allen had read many articles about
5 vitamin B12 and that he “knew that literature very well.” (Id.) This does not show he had
6 knowledge of any specific products, nor that he intended to deceive the PTO. This allegation is
7 therefore insufficient to support a claim of inequitable conduct.

8 2. Berlin Articles

9 Defendant next alleges that the inventors failed to disclose two articles authored by
10 Berlin, et al., in 1968 and 1978 (“Berlin 1” and “Berlin 2”), that discuss the use of vitamin B12.
11 (Dkt. No. 8 at 19.) However, Defendant never alleges that the inventors had actual knowledge of
12 the information in these articles. The closest that Defendant comes to alleging specific
13 knowledge is stating that Allen possesses a book containing the Berlin 2 article. (Dkt. No. 8 at
14 20.) However, mere possession is insufficient to show that Allen read the specific article in
15 question or that he intentionally withheld it from the PTO. Therasense, 649 F.3d at 1290.

16 Defendant also alleges that Stabler and Allen knew about the Berlin articles because they
17 referenced them in journal articles they published in 1997 and 2002. (Dkt. No. 8 at 30-32.)
18 However, even if the Court were assume that referencing an article equates to having intimate
19 knowledge of the article’s contents, this does not prove intent to deceive. “Proving that the
20 applicant knew of a reference, should have known of its materiality, and decided not to submit it
21 to the PTO does not prove specific intent to deceive.” Therasense, 649 F.3d at 1290.

22 Finally, Defendant fails to show that the Berlin articles are material to the ‘496 Patent.
23 Both articles discuss uses of vitamin B12, but the ‘496 Patent teaches the combination of three
24 different compounds, not just one. (Dkt. No. 20 at 10.) Defendant makes no showing that, but-for

1 the withholding of the Berlin articles, the '496 Patent would not have been granted. This
2 allegation is therefore insufficient to support a claim of inequitable conduct.

3 3. Allen Articles

4 Defendant next alleges that the inventors failed to disclose articles co-authored or
5 authored by inventor Allen in 1978, 1982, and 1991. (Dkt. No. 8 at 21-22.) The 1978 article, lead
6 authored by Fred Kolhous, et al., and co-authored by Allen, discusses serum levels of vitamin
7 B12. (Id.) The 1982 article, lead authored by Allen, discusses the use of oral vitamin B12 and
8 folate. (Id. at 22.) The 1991 article, lead authored by Frank A. Lederle, and co-authored by
9 Allen, discusses the use of oral vitamin B12 therapies in the United States. (Id. at 22-23.) While
10 these articles cover subject matter related to the '496 Patent, Defendant fails to provide specific
11 facts that establish the "what, when, where, and how" of any alleged material misrepresentations
12 that Allen committed before the PTO. Exergen, 575 F.3d at 1329.

13 Regarding the 1978 article, Defendant provides no facts showing how the level of
14 vitamin B12 levels in serum is material to claim 1 of the '496 Patent for an oral formulation with
15 both vitamin B12 and folic acid. Regarding the 1982 and 1991 articles, Defendant provides no
16 facts showing how these articles are material to any claim of the '496 Patent. With regard to all
17 three articles, Defendant offers no facts that support the conclusion that Allen had the specific
18 intent to withhold information from the PTO. Therasense, 649 F.3d at 1285. These allegations
19 therefore fail.

20 4. Jansen Patent

21 Defendant next alleges that Plaintiffs made misrepresentations about United States Patent
22 No. 4,945,083 (the '083 Patent), issued to Dr. Christian Jansen, Jr. (Dkt. No. 8 at 24.) Although
23 the inventors disclosed the '083 Patent to the PTO, Defendant alleges that the inventors and their
24 attorney represented to the PTO that the upper limit of vitamin B12 taught by the '083 Patent

1 was only 1.0 mg, when in fact the '083 Patent encompasses levels of 2.0 mg and higher. (Dkt.
2 No. 8 at 24.) Defendant also alleges that the inventors and their attorney “represented that no one
3 else had ever before contemplated combining all three vitamins together in one formulation,
4 which is false and a material misrepresentation of fact because such combination and/or use was
5 known and had been available for use in the prior art” (Id. at 25.)

6 While these allegations may have sufficed before Exergen and Therasense, they are
7 insufficient under current Federal Circuit law. Defendant fails to allege who specifically made
8 these representations, when they were made, or how any representations were material. (Dkt. No.
9 20 at 12); Exergen, 575 F.3d at 1329. “Pleading on ‘information and belief’ is permitted under
10 Rule 9(b) when essential information lies uniquely within another party’s control, but only if the
11 pleading sets forth the specific facts upon which the belief is reasonably based.” 575 F.3d at
12 1330. Defendant fails to plead any specific facts that form a reasonable basis for these
13 allegations. They are therefore insufficient to support a claim for inequitable conduct.

14 5. Allen’s Prior Art

15 Defendant next alleges that two articles authored by Allen “clearly taught the
16 combination of B12 and folate” and that “[m]isrepresentations to the contrary were clearly
17 material and erroneous particularly in light of the fact that such art and information was not
18 disclosed to the Patent Office.” (Dkt. No. 8 at 28.) These articles—a 1982 article in the Journal
19 of Clinical Investigation and a 1983 article in the journal Obstetrics & Gynecology—discuss the
20 properties of commercially available products containing vitamin B12 and folate. (Id.) However,
21 Defendant offers no facts suggesting that Allen had any deliberate intent to deceive the PTO by
22 not disclosing these articles. (Id.); 575 F.3d at 1329. In fact, Plaintiffs offer a reasonable
23 explanation for why these articles were not disclosed to the PTO: the products studied by the
24 articles contained tiny amounts of vitamin B12, less than one percent of the amount of vitamin

1 B12 required to treat vitamin deficiency. (Dkt. No. 20 at 13.) Because Defendant does not allege
2 specific facts supporting an inference of materiality or intent to deceive, this allegation fails to
3 support a claim for inequitable conduct.

4 6. Example 2 in the Specification of the '496 Patent

5 Defendant next alleges that the inventors and their attorney presented Example 2 in the
6 specification of the '496 Patent in a misleading way because they failed to disclose that the
7 referenced study was conducted mostly in Germany by others who were not inventors, and that
8 the active components of the injections used in that study were essentially the same as a
9 commercial product previously available. (Dkt. No. 8 at 28-29.) However, Defendant again fails
10 to allege facts suggesting any deliberate intent to deceive the PTO. Exergen, 575 F.3d at 1329.
11 Rather than showing deliberate intent to deceive, the deposition testimony cited by Defendant
12 supports the opposite inference: Allen did not disclose the commercial availability of the product
13 because he did not think it was relevant to the oral preparation that was the subject of the '496
14 Patent. (Dkt. No. 20 at 13-14.) This allegation does not contain sufficient facts to support a claim
15 for inequitable conduct.

16 7. Statements During Prosecution of Prior Patents

17 Defendant next alleges that the inventors or their attorney failed to disclose prior art
18 during the prosecution of two patents in the ancestry of the '496 Patent: U.S. Patent Nos.
19 5,795,873 and 6,297,224. However, Defendant does not allege any basis for considering these
20 patents in the current case. (Dkt. No. 8 at 29-31.) Rather, Plaintiffs suggest that Defendant "may
21 have just missed the fact that these two additional patents, which are not at issue in this lawsuit,
22 were at issue in the prior litigation from which [Defendant] simply copied these allegations."
23 (Dkt. No. 20 at 14.) This appears to be the case, because Defendant does not address these
24 patents at all in its opposition to the current motion. (Dkt. No. 21; Dkt. No. 22 at 8.) In the

1 absence of any showing of why these patents are relevant, Defendant's allegations regarding
2 these patents fail to support a claim for inequitable conduct.

3 8. Statements During Prosecution of '496 Patent

4 Defendant next alleges that the inventors filed a Disclosure Statement with an Election
5 and Amendment during the prosecution of the '496 Patent that contained misrepresentations
6 made to the examiner in prior negotiations. (Dkt. No. 8 at 33-34.) Defendant asserts that these
7 filings included "previously presented arguments . . . in addition to the Examiner's
8 Amendments/Reasons for Allowance in the '496 Patent." (*Id.* at 33.) Defendant also asserts that
9 the Examiner relied upon these representations. (*Id.* at 34.)

10 However, Defendant does not identify with any degree of specificity the content of these
11 misrepresentations, nor who made them. (Dkt. No. 8 at 33-34.) While Defendant's opposition to
12 the present motion contains some additional detail—stating, for example, that the statements
13 related to the prior art allegedly teaching away from the combinations of vitamins claimed in the
14 '496 Patent—a party cannot correct deficiencies in a pleading through statements made in
15 motion papers. *See, e.g., Wright v. Ernst & Young LLP*, 152 F.3d 169, 178 (2d Cir. 1998).
16 Defendant's claims regarding statements made during prosecution of the '496 Patent are
17 insufficient to support a claim for inequitable conduct.

18 9. Statements Regarding Motivation to Combine

19 Defendant next alleges that the inventors and their attorney knew that a statement made
20 in an Information Disclosure Statement that "there was no motivation for the combination of the
21 present invention, containing both folate and B12 or all three of folate, B12 and B6" was false as
22 of Aug. 5, 1993. (Dkt. No. 8 at 35.) However, while Defendant alleges intent to deceive on a
23 general level, it offers no facts supporting an inference that the inventors intended to deceive the
24 PTO. (*Id.*) Defendant also fails to explain why this information is material, especially given the

1 very small amount of vitamin B12 in the prior formulation at issue. (Dkt. No. 20 at 15.)

2 Therefore, this allegation fails to support a claim for inequitable conduct.

3 10. Failure to Disclose Medivitan

4 Defendant next alleges that the inventors and their attorney failed to disclose to the PTO
5 that the '496 Patent is based in large part on data from an injectable product called Medivitan,
6 which contained a similar combination of compounds. (Dkt. No. 8 at 36-38.) Defendant alleges
7 that "Allen was aware that such a compositionally similar injectable formulation provided the
8 basis for the supporting data for the claimed oral formulations and their use in the '496 Patent."
9 (Id. at 37.) However, the portion of the Allen testimony which Defendant cites to support this
10 allegation does not mention Medivitan. (Id.) Defendant also offers no facts that support an
11 inference that Allen had a specific intent to deceive the PTO. (Id.) In fact, Plaintiffs' assertion
12 that disclosure of Medivitan would have been cumulative in light of the '083 Patent, which was
13 disclosed to the PTO, seems a more reasonable explanation for why the information was not
14 disclosed. (Dkt. No. 20 at 16.) Defendant's claim regarding Medivitan is insufficient to support a
15 claim for inequitable conduct.

16 11. Failure to Disclose Oral Preparations in the '496 Patent Specification

17 Finally, Defendant alleges that the inventors engaged in inequitable conduct because they
18 "were aware that there were no oral preparations used at any location in the patent application
19 leading to the granting of the '496 Patent." (Dkt. No. 8 at 38.) However, Defendant offers no
20 details explaining why failing to discuss oral preparations in the specification of the '496 Patent
21 would be material. (Id.) The deposition testimony cited by Defendant actually supports the
22 opposite conclusion: While B6, B12, and folic deficiencies had been treated with pills for many
23 years, no one had yet developed an oral formulation encompassing all three vitamins. (Dkt. No.
24 8-3 at 29-30.) Defendant offers no facts to support a finding that disclosing the oral preparation

1 of these compounds would have had a material impact on the PTO's approval of the '496 Patent.
2 Therasense, 649 F.3d at 1291. Therefore, this allegation does not support a claim for inequitable
3 conduct.

4 **Conclusion**

5 Because all eleven examples of misrepresentations or omissions offered by Defendant
6 fail to meet the level of specificity and materiality required by Federal Rule 9(b), as well as
7 Exergen and Therasense, Defendant's counterclaim for inequitable conduct is DISMISSED.

8 The clerk is ordered to provide copies of this order to all counsel.

9 Dated this 8th day of August, 2012.

10
11 

12 Marsha J. Pechman
13 United States District Judge
14
15
16
17
18
19
20
21
22
23
24